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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,431

07/27/2006

Hikaru Kai

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

12/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,431	KAI ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/19/2010</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> . |

DETAILED ACTION

The Amendment filed October 21, 2010 in response to the Office Action of July 22, 2010 is acknowledged and has been entered. Claim 8 has been canceled. Claim 1 has been amended. Claims 1-3 and 7 are pending and under examination in this Office action.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Art Unit 1648.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequence set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason (s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 – 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The sequence listing and its computer readable form submitted on 7/27/2006 are defective see notice on 1/30/2009. Applicant response on 5/6/2010 failed to comply with the sequence rules. Applicant is required to provide a new sequence listing and its computer readable form. Additionally, Applicant is required to add SEQ ID NO to the sequences listed in the specification on page 8 and in all other places in the specification where the sequences are recited.

Applicant can respond to this notice together with the response to this Office action.

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Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filling a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice of Comply with the response.

The addresses below are effective 5 June 2004. Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebs/efs/downloads/documents.htm>,
EFS Submission user Manual – ePAVE)
2. Mailed to:
Mail Stop Sequence
Commissioner for Patents
P.O. Box 22313-1450
3. Hand Carry, Federal Express, United parcel Service or other
delivery service to:
U.S. Patent and Trademark Office
Mail Stop Sequence
Customer Window
Randolph Building
Dulaney Street
Alexandria, VA 22314

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/19/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Rejection to Claim 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is moot** because Applicant canceled the claim.

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Rejection of Claims 1-3, 7 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 103

Rejection of Claims 1-3 and 7 under 35 U.S.C. 103(a) as being unpatentable over Sanderson and Smith (Journal of Virology, 1998), Kistner et al. (Developments in Biological Standardization, 1999) and Reiter and Mundt (US PGPub 2003/0108860) **is withdrawn** in view of Applicant's arguments and amendment.

New Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillegas et al. (US Patent 6,214,618 B1) in view of Ferrari et al. (US Patent 6,184,348 B1).

Hillegas teaches methods of producing herpesvirus comprising adhering cells to a microcarrier support comprising multiple copies of the cell attachment ligand the Arg Gly Asp (RGD) peptide of present SEQ ID NO: 70 and the ProNectin F peptide (see claims 1-13, column 2, lines 19-41, column 3, lines 15-27, column 4, lines 35-62, and Example 2. The method taught by Hillegas comprises culturing the adhesive cells in a medium free of animal origin

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components, subculturing the cells using the cell dispersing agent such as EDTA or trypsin and inoculating and proliferating the virus in the cells. (see Figures 1-3, and Examples 1 and 2).

While Hillegas teaches ProNectin F Hillegas does not expressly teach the sequence of Gly Ala Gly Ala Gly Ser (GAGAGS) of present SEQ ID NO: 74. Hillegas does not teach the number-average molecular weight (Mn).

Ferrari teaches polymer polypeptides Gly Ala Gly Ala Gly Ser (GAGAGS) of present SEQ ID NO: 74 and Arg Gly Asp (RGD) peptide of present SEQ ID NO: 70 (see claims 4 and 5). Ferrari teaches that the GAGAGS and RGD polypeptides are cell growth and attachment factors (Example 3). Ferrari teaches molecular weight of the GAGAGS and RGD polymers from 90, 150, 250, 300, 500 to 3640 kDal (see Example 3).

It would have been prima facie obvious to provide Hillegas microcarrier support comprising Ferrari's polymer polypeptides Gly Ala Gly Ala Gly Ser (GAGAGS) and Arg Gly Asp (RGD) because Ferrari teaches that the GAGAGS and RGD polypeptides are cell growth and attachment factors (Example 3).

It would have been obvious to optimize the amount and the molecular weight of the polymer polypeptides Gly Ala Gly Ala Gly Ser (GAGAGS) and Arg Gly Asp (RGD). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Optimizing experimental conditions, including the amount of the compound used, falls within the skills of an ordinary artisan. If the amount of the polymer used in the claimed methods produces an unexpected result, applicant needs to point out what the unexpected results are. Generally, differences in

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concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235(CCPA 1955).

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/
Examiner, Art Unit 1648